

### **REMARKS/ARGUMENTS**

Claim 3 has been rejected. Claims 1 and 2 remain withdrawn as being drawn to non-elected inventions following the Restriction Requirement of March 9, 2005, but have not been cancelled by Applicants in view of possible later rejoinder under MPEP §821.04.

Claim 3 has been amended to recite that the claimed monolayer comprises stripped phage, support for which may be found throughout the specification but particularly on page 7, lines 11 to 22, page 16, lines 5 to 27, and the paragraph spanning pages 17 and 18. Accordingly, no new matter has been added by way of amendment.

This claim amendment was not presented earlier as Applicants earnestly believe that the previously presented claim recited patentable subject matter. The Examiner is respectfully requested to enter this claim amendment to further prosecution or to place the application in better condition for appeal.

Claim 3 is pending in the application. Reconsideration of these claims is respectfully requested in view of the aforementioned claim amendment and the following remarks. The Examiner's comments in the Office Action dated December 28, 2005 are addressed below in the order set forth therein.

#### **The Rejection of Claim 3 under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn**

Claim 3 remains rejected under 35 U.S.C. §112, second paragraph, as being indefinite because "It is unclear what product limitations result from the process ... it is unclear if the monolayer must comprise a stripped phage" (see Office Action dated December 28, 2005, page 2, item 2). As stated above, claim 3 has been amended to recite that the claimed monolayer comprises stripped phage. Accordingly, Applicants respectfully submit that this rejection has been obviated and request that it be withdrawn.

#### **The Rejections Under 35 U.S.C. §102(b) Should Be Withdrawn**

Claim 3 remains rejected under 35 U.S.C. §102(b) as being anticipated by each of the following references: 1) Hengerer *et al.* (1999) *Biosensors & Bioelectronics* 14:139-144; 2) Benjamin *et al.* (U.S. Pat. App. 20010006778); and 3) Uttenthaler *et al.* (1998) *Analytica*

*Chimica Acta* 362:91-100. Because of the similarity of these rejections, they will be dealt with together below. Applicants respectfully traverse these rejections and request that they be withdrawn.

The basis of the Examiner's rejections in view of each of the cited references is her assertion that each reference teaches a monolayer and that because "[i]t is unclear what further product limitations would be provided by the recited method" each of these references teach the product recited in claim 3 (see Office Action dated December 28, 2005, page 3, item 5). The Examiner states that for product-by-process claims the determination of patentability is based on the product itself, and that "[a]ny further product limitations, such as if the monolayer comprises a stripped phage, must be claimed as part of the monolayer product" (see Office Action dated December 28, 2005, page 5).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As amended, claim 3 recites that the claimed monolayer comprises stripped phage. Accordingly, none of the cited references meet all of the limitations of claim 3.

The Hengerer *et al.* reference does not describe or even mention stripped phage for use as a component of a monolayer. Instead, the Hengerer *et al.* reference describes screening phage libraries using a quartz crystal microbalance (QCM) device in order to identify recombinant antibodies and mutants of human pancreatic secretory trypsin inhibitor (hPSTI) that bind to an antigen, namely a recombinantly expressed fragment of the major outer membrane protein (MOMP) of *Legionella pneumophila* (on p. 140, column II, first full paragraph of the Hengerer *et al.* reference). The reference states that "[t]he combination of phage display techniques and antigen-coated QCM allows the screening of large phage libraries without specifically labeled analytes in contrast to testing by ELISA" (see p. 140, column I, last full paragraph of the Hengerer *et al.* reference). The quartz crystal microbalances of Hengerer *et al.* were coated with streptavidin and biotinylated MOMP and then used to screen phage libraries for complementary antibodies or "affibodies" (page 140, column II, last paragraph through page 141, column I, first paragraph of the Hengerer *et al.* reference). Thus, the Hengerer *et al.* reference describes the use

of sensor devices coated with biotinylated MOMP to screen phage libraries, but does not teach or even suggest monolayers comprising stripped phage that are created using a particular purification process as in current claim 3.

The Benjamin *et al.* reference also fails to describe or even mention stripped phage for use as a component of a monolayer. The Benjamin *et al.* reference “features methods for identifying compounds that bind a target that combine the use of peptide-based libraries with the use of chemically-based libraries...” (see paragraph 0005 *et seq.* of the Benjamin *et al.* reference). The reference describes a monolayer of cells that express LHRH-R (luteinizing hormone releasing hormone receptor) and their use to identify members of a phage library that bind to LHRH-R (see paragraph 0058 of the Benjamin *et al.* reference). However, the Benjamin *et al.* reference does not teach or even suggest a monolayer comprising stripped phage prepared by a specific purification process as provided in claim 3.

Finally, the Uttenthaler *et al.* reference also fails to describe or even mention stripped phage for use as a component of a monolayer. The Uttenthaler *et al.* reference teaches an immunosensor for the detection of African Swine Fever (ASF) disease in pigs. The immunosensor is coated with the ASF protein VP73. The reference does not discuss the use of phage at all. Further, as shown in Table 1 of the Uttenthaler reference (p. 95, discussed on p. 99, column I, second full paragraph), the optimum incubation period for the VP73 immunosensor is four days. This contrasts with the properties of sensor devices coated with monolayers formed according to the method of claim 3, which provide rapid and reliable measurements as illustrated by working Example 1 (specification pp. 29-31; see also data shown in Figure 4 and described in the Figure 4 figure legend on specification p. 6). Thus, the Uttenthaler reference does not teach or even suggest a monolayer comprising stripped phage prepared by a specific purification process as provided in claim 3.

Because none of the Hengerer *et al.*, Benjamin *et al.*, or Uttenthaler *et al.* references teach or even suggest a monolayer comprising stripped phage prepared by a specific purification process as provided in claim 3, none of these references meet all of the limitations of claim 3. Accordingly, Applicants respectfully request that the rejections of claim 3 under 35 U.S.C. §102(b) in view of these references be withdrawn.

The Obviousness-Type Double-Patenting Rejections Should Be Withdrawn

Claim 3 remains provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over: 1) claim 18 of co-pending App. No. 09/452, 968; 2) claim 20 of co-pending App. No. 10/068,570; and 3) claims 1 and 3 of co-pending App. No. 10/289,725. Because of the similarity of these rejections, they will be dealt with together below. Applicants respectfully traverse these rejections and request that they be withdrawn.

The basis of the Examiner's rejections is similar to that for the 35 U.S.C. §102(b) rejections described above, in that without any further product limitations in claim 3, the Examiner reads the claim as encompassing virtually any monolayer. Because each of the cited claims in the co-pending applications described above are directed to monolayers, the Examiner asserts that these claims are not patentably distinct from claim 3.

An obviousness-type double patenting rejection is improper where claims are patentably distinct over the claims of the patent or application to which they are being compared. See *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278, 23 USPQ2d 1839, 1843 (Fed. Cir. 1992); *In re Borah*, 354 F.2d 1272, 1278, 23 USPQ 213, 221 (CCPA 1969). Such a rejection is improper where non-identical claims are nonobvious over the claims upon which they were rejected. See *In re Gladrow*, 406 F.2d 1376 (CCPA 1969). Furthermore, one of the necessary elements for establishing a *prima facie* case of obviousness is that the prior art reference(s) must teach or suggest all the claim limitations. MPEP §2143, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

As amended, claim 3 recites that the claimed monolayer comprises stripped phage. Claim 18 of co-pending App. No. 09/452, 968 is directed to a monolayer consisting essentially of serum. Claim 20 of co-pending App. No. 10/068,570, although cancelled in a Preliminary Amendment filed January 6, 2004, was nonetheless originally directed to a ligand sensor device comprising, among other things, a layer essentially comprising a peptide of interest on top of a coupling composition layer. Claims 1 and 3 of co-pending App. No. 10/289,725 are directed to a phage ligand sensor device comprising, among other things, a binding element comprising

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engineered phage where the binding element is coupled to a sensor by a layer of biotinylated lipid. None of these claims teach or even suggest a monolayer comprising stripped phage prepared by a specific purification process as provided in claim 3.

Because none of the cited claims in co-pending App. Nos. 09/452, 968, 10/068,570, or 10/289,725 teach or suggest to one of skill in the art a monolayer comprising stripped phage prepared by a specific purification process as provided in claim 3, none of these references teach or suggest all of the limitations of claim 3. Accordingly, Applicants request that the rejections of claim 3 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

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### CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under the judicially created doctrine of obviousness-type double patenting and under 35 U.S.C. §§112, second paragraph, and 102(b) are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

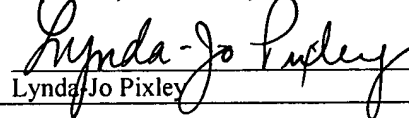


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